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| EXAMINER | |
|---|---|
| SUNDARARAMAN, VIKRAM P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3735 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/631,882 | SCHULZ ET AL. | |
| | Examiner | Art Unit | |
| | Vikram P. Sundararaman | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/31/2003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. During a telephone conversation with Lauren Keller (Customer No. 20,995) on April 18, 2006 at 2:19PM a provisional election was made without traverse to prosecute the invention of **Group I, Claims 1-21.** Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. **Claims 1-21**, drawn to an ear sensor and an oximetry sensor, classified in class 600, subclass 310;

II. **Claims 22-25**, drawn to a method of attaching a sensor to a measurement site to reduce pressure necrosis, classified in class 600, subclass 386; and

III. **Claims 26-27**, drawn to a method of assembling an oximetry sensor, classified in class 600, subclass 310.

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product.

4. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

***Claim Rejections – 35 USC § 112***

5. Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 20 recites the limitation, "wherein the plurality of opposing members removably position said silicone lenses against a patient's ear" in Lines 2-3 of the claim. In this instance, the human body is non-statutory subject matter and cannot positively be claimed. To overcome this rejection, for example, Lines 2-3 of Claim 20 should be replaced with, "wherein the plurality of opposing members is capable of removably positioning said silicone lenses against a patient's ear."

### *Claim Rejections - 35 USC § 112*

6. **Claim 16** recites the limitation "said cable" in Line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. **Claim 18** recites the limitation "said tissue site" in Line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim

8. **Claims 17 and 18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims, "said clip housing exerts a force on said tissue in the range of about 90g to about 140g," [Claim 17, Lines 1-2] and "said clip housing exerts a force on said tissue site in the range of about 115g to about 130g." [Claim 18, Lines 1-2] It is well known in the art that "g" units are not units of force and therefore it is unclear as to what the applicant is claiming in this limitation.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Goldberger et al., US 4,685,464, hereinafter referred to as "Goldberger-1."

3. As to **Claim 1**, Goldberger-1 teaches ***an ear sensor:*** "durable sensor for detecting optical pulses" [Title] that includes:

a. ***An emitter which emits light of at least first and second wavelengths:*** "Light source, 90, preferably comprises a red Led and an infrared LED that are strobed sequentially under the control of the blood constituent measuring instrument in accordance with procedures known to those skilled in the art. The red LED preferably operates at a wavelength of about 660 nanometers and the infrared LED operates at about a wavelength of about 920 nanometers," [Column 8, Lines 6-12];

b. ***A light sensitive detector which provides intensity signals resulting from detection of at least first and second wavelengths of light after the light is attenuated by the body tissue carrying the pulsing blood:*** "photodetector, 100" [Column 8, Line 3]

c. ***A clip housing:*** [See FIG 3.], ***including one or more windows through which the light or the attenuated light will pass:*** "Slit, 113, is provided in depression, 198, so that small integrated circuit, 102 or 92, cab be inserted in to depression, 198, from inside the cavity formed by walls, 182-185, and tissue contacting surface, 190."Thus light source, 90, or light detector, 100, can be placed inside the depression and arranged so that the light emitting side or the light detecting side faces the opposing pad." [Column 8, Lines 58-64]; and

*d.* ***A plurality of tissue contacting surfaces configured to be positioned between the emitter and the tissue and between the detector and the tissue***

***when the clip housing is applied to the site, wherein the plurality of tissue contacting surfaces include pliable or adhesive material that provide increased support for removably retaining the tissue contacting surfaces proximate to the tissue:*** "Tissue contacting surface, 190, comprises spaced apart parallel ridges, 192 and 194, terminating in walls, and concave cylindrical section, 196, interconnecting ridges, 192 and 194," [Column 8, Lines 48-51] and that "other transmissive sensor designs have the light source and light detector mounted in a flexible structure having adhesive surface for taping the sensor securely around the tissue..." [Column 2, Lines 44-47] Furthermore, Goldberger-1 teaches, "Adherent sensors have the advantage that they do not move relative to the tissue, thus reducing the cause of at least one source to measurement error, sensor movement." [Column 3, Lines 56-59].

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 2-3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Golderger-1, in view of Goldberger et al, US 5,676,139, hereinafter referred to as "Goldberger-2."

6. As to **Claim 2**, Goldberger-1 teaches the limitations of Claim 1 as discussed previously in this action. What Goldberger-1, however, does not teach is ***wherein said tissue contacting surfaces comprise adhesive tabs.*** Goldberger-2 teaches a "spring probe clip housing," in which it is taught that, "in order to prevent the movement of the patient's finger, 3, within the probe housing, 1, the adhesively coated material, 121, located in the second section, 12, is implemented by means of at least one and preferably a plurality of layers of clear conformable material, 500, that are adhesively coated on both sides thereof." [Column 4, Lines 25-32] Both Goldberger-1 and Goldberger-2 teach spring clips for housing probes used for pulse oximetry. Therefore, it would have been obvious for one with ordinary skill in the art, at the time of the invention to modify the sensor of Goldberger-1 with the teachings of Goldberger-2 to include adhesive tabs on the tissue contacting surfaces, in order to prevent movement of the sensor housing as taught by Goldberger-2.

7. As to **Claim 3**, Goldberger-2 teaches ***wherein said adhesive tabs are removable:*** "the layers of conformable material 500 can be provided with a pull tab 503 such that after a plurality of uses, when the adhesive 501,502 is reaching end of life, the user can withdraw that layer of conformable material 500 to expose the layer of conformable material beneath, providing an unused adhesive available for use." [Column 4, Lines 38-44]

8. **Claims 4-12 and 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberger-1 in view of Weckstrom et al., US 6,041,247, hereinafter referred to as "Weckstrom."

9. As to **Claims 4 and 19**, Goldberger-1 teaches the limitations of Claim 1 as discussed previously in this action. [Also see Goldberger-1, FIGS. 3 and 4a-4g] What Goldberger-1, however, does not teach is ***wherein the tissue contacting surfaces comprise silicone lenses.*** Weckstrom teaches a "non-invasive optical measuring sensor and measuring method," in which, "the window may be constructed e.g. of silicone or some other appropriate material. Another option is to fill the entire cavity, 18, with a light transmitting material, for example with similar transparent silicone." [Column 7, Lines 39-42]. Both Goldberger-1 and Weckstrom teach optical sensors that are capable of being attached to a patient's skin. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to use a silicone window, as it would have been an obvious substitution of one known equivalent window for another.

10. As to **Claim 5**, Weckstrom teaches ***wherein said silicone lenses are pliable:*** "commercially available silicone polymers, [which] are readily mouldable to a proper shape." [Column 8, Lines 19-20]

11. As to **Claim 6**, it is an inherent feature of the transparent silicone material that fills the window to increase a coefficient of friction between the silicone lens and a tissue site. This it is additionally taught by Goldberger-1 that silicone possesses the qualities of, but not limited to, "resiliency, flexibility, durability, and resistance to solvents, the ability to clean silicone in accordance with common medical practices, and a relatively

high coefficient of friction relative to skin, i.e., about 0.95, so that it will not easily slide off a clamped finger."

12. As to **Claim 7**, Weckstrom teaches, wherein at least one of said silicone lenses is sized to have a surface area greater than a surface area defined by at least one of the windows: [See FIG 3, Item 16]

13. As to **Claim 8**, Weckstrom teaches, ***wherein optical properties of said silicone lenses are substantially similar to optical properties of glass:*** The silicone window, 16, taught by Weckstrom is described as a light transmitting material and therefore is similar to the optical properties of glass.

14. **Claim 9**, is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability us based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *See In re Thorpe 777 F.2d 695, 698, 227 USPQ 964, 966.* In this way, **Claim 9** is rejected under 35 USC 103(a) as the combination of Goldberger-1 in view of Weckstrom teaches a silicone window as previously described in this action. Alternatively, the examiner takes official notice that it is well known in the art to fabricate silicone materials by the process injection molding. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to make the silicone lens by the process of injection molding.

15. As to **Claims 10-12,** applicant has not stated the exact shape of the lenses is for a specific purpose or that it solves a stated problem. As such, the exact shape would have been a mere matter of design choice for one skilled in the art.

16. As to **Claim 20**, Goldberger-1 teaches ***wherein the plurality of opposing members removably position said silicone lenses against a patient's ear:*** "The measurements rely on noninvasive sensors that are placed against the patient's tissue at a location where the tissue is well perused, for example, a fingertip, a toe, the earlobe, the nasal septum, the forehead, the umbilical cord, and the like." [Column 1, Lines 14-19]

17. As to **Claim 21**, Goldberger-1 teaches, ***wherein opposing members further comprise a plurality of extended ridges adapted to assist in releasing said plurality of opposing members from said tissue site:*** "Two spaced apart longitudinal ridges are molded into the pad at the longitudinal edges of the long side of the cylindrical surface." [Column 5, Lines 23-26]

18. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberger-1 in view of Pastrick et al., US 2004/0115607 A1, hereinafter referred to as "Pastrick." Goldberger-1 teaches the limitations of the claimed invention as described previously in this action. What Goldberger-1 does not teach is ***wherein said clip housing comprises a disposable clip and said emitter and detector are removable from said clip.*** Pastrick teaches an "electrode clip, 140, as best shown in FIGS. 4-6, comprises two main components made of any suitable non-conductive material such as

plastic. The first main component of the electrode clip, 140, is the housing, 142, which has a first and second mating member, 144 and146, which together form a slot, 148, for receiving an electrode training pad, 120, therein. The second main component of the clip 140 is the securing means 160 which secures the electrode training pads 120 to the clip 140." [Paragraph 0021] Goldberger and Pastrick both teach the attachment of medical diagnostic equipment, be it an electrode pad or an emitter and detector assembly of an oximeter, to a patient via a clip. It would have therefore been obvious for one with ordinary skill in the art at the time of the invention to modify the clip housing taught by Goldberger with the teachings of Pastrick to include such a disposable clip wherein the emitter and detector could be removable from the clip, in order to facilitate clean clip housings to patients in which a sensor can be attached easily.

19. **Claims 14-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberger-1 in view of Mehler et al., US 2004/0115607 A1, hereinafter referred to as "Mehler." As to **Claim 14**, Goldberger teaches the limitations of the claimed invention as described previously in this action. What Goldberger does not teach is the ear sensor ***further comprising an attachment supplement.*** As to **Claim 15**, Goldberger teaches the limitations of the claimed invention as described previously in this action. What they do not teach is the ear sensor ***according to Claim 14, wherein the attachment supplement comprises an ear hanger adapted to fit around an ear portion so as to support at least a portion of the ear sensor weight.*** Mehler teaches an earpiece light that "comprises an ear support, preferably for placement

behind the user's crest of helix." [Paragraph 0004 and FIGS. 1-6] It is inherent that the ear support taught by Mehler is used to support at least a portion of the earpiece. The ear support of Mehler, also teaches the limitation set for in **Claim 16**, of the claimed in invention as it includes: ***a formable stem having a first end and heaving a second end; a generally semi-circular bend proximate said first end; a generally right angle bend proximate the second end; and a holder attached to the second end.*** [See FIGS. 1-6] Since both Goldberger and Mehler teach devices that bear loads on the ear, it would have been obvious for one with ordinary skill in the art, at the time of the invention, to modify the ear sensor taught by the combination of Goldberger to include the ear support of Mehler, to support at least a portion of the sensor weight.

20. As to **Claims 17 and 18,** applicant has not stated the force that the clip housing exerts on the tissue site in the range of 90g to 140g or in the range of 115g to 130g is for a specific problem or solves a stated problem. As such, the exact force limitation would have been a mere matter of design choice for one skilled in the art.

***Conclusion***

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes:

e. Chung et al., US 5,247,932;

f. Larson, US 6,505,061 B2;

g. O'Neil, US 6,748,254 B2;

h. Hicks et al., US 6,745,061 B1; and

i. Taylor et al., US 5,913,819.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 830am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A Marmor, II
SPE, Art Unit 3735

VPS